



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Chr

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/283,702 04/01/99 BARRY

D 9045-2

020792 LM02/1006
MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH NC 27627

EXAMINER

HAYES, J

ART UNIT	PAPER NUMBER
----------	--------------

2761

DATE MAILED:

10/06/99

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

—

Office Action Summary

Application No.

09/283,702

Applicant(s)

BARRY ET AL.

Examiner

John W Hayes

Art Unit

2761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13-33, 36-55 and 58-69 is/are rejected.
- 7) ☒ Claim(s) 11, 12, 34, 35, 56 and 57 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 1999 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2
- 17) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other:

Art Unit: 2761

DETAILED ACTION

Drawings

1. The drawings filed on 1 April 1999 are subject to correction of the informalities indicated on the attached "Notice of Draftperson's Patent Drawing Review," PTO-948. In order to avoid abandonment of this application, correction is required.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: reference sign "A2" listed in the specification page 37, line 26 is not indicated on Figure 12B. Correction is required.
3. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 4, 21, 27, 44, 47, 50 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As per claims 4, 27 and 50, the limitation "and information for drug treatments for other conditions" recited in the claim could include any number of patient conditions and renders the claim indefinite, since one of ordinary skill in the art is not able to determine the scope of the claim.

As per claims 21, 44 and 66, the claim language refers to "said knowledge base" of claim 1 when there are three knowledge bases recited claim 1. It is not clear to the examiner which knowledge base the applicant is referring to. For purposes of the prior art rejection which appears below, it is assumed by the examiner that the applicant is referring to the first knowledge base.

Art Unit: 2761

As per claim 47, the claim recites "computer readable program code means for generating a computing device comprising...". It is not clear to the examiner exactly what the applicant is claiming. Computer readable program means will typically direct a computer or other programmable data processing apparatus to function in a particular manner or cause a series of operational steps to be performed to produce a computer implemented process. It is not clear to the examiner the series of operational steps that are performed by the computer readable program code means to generate a computing device comprising several knowledge bases.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3, 5-10, 13-26, 28-33, 36-49, 51-55, and 58-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over *McAndrew et al*, U.S. Patent No. 5,517,405 in view of *Evans et al*, "A Computer-Assisted Management Program for Antibiotics and Other Antiinfective Agents" [hereinafter referred to as *Evans et al*] and *Pazanni et al*, "Application of an Expert System in the Management of HIV-Infected Patients" [hereinafter referred to as *Pazanni et al*].

As per claims 1 and 24, *McAndrew et al* discloses an expert system for providing interactive assistance which is useful in managing the health care of individual patients and teaches a method and system for "guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition comprising providing patient information to a computing device (See Figure 2, Col. 2, lines 37-41 and Col. 6, lines 29-51) comprising a knowledge base with a plurality of expert rules for evaluating and selecting a therapeutic treatment regimen for a disease or medical condition" (See Figure 1, Col. 3, lines 6-17 and 49-53, and Col. 7, lines 45-54). *McAndrew et al* also discloses a database of

Art Unit: 2761

information and synopses which are relevant to the disease or medical condition of the patient (See Col. 6 line 62-Col. 7 line 4 and Col. 7, lines 37-44), however, does not explicitly disclose a plurality of different therapeutic treatment regimens for a particular disease or advisory information useful for the treatment of a patient with different constituents of the different therapeutic treatment regimens. *McAndrew et al* also does not explicitly disclose generating a listing of available therapeutic treatment regimens for the patient. *Pazanni et al* discloses a rule-based expert system that recommends drug regimens for treatment of HIV infected patients and teaches a knowledge base comprising a plurality of different therapeutic treatment regimens for a disease or medical condition (See page 359) and generates in the computing device a ranked listing of available therapeutic treatment regimens for the patient (See page 357 Column 1). *Evans et al* discloses a computerized program that recommends antiinfective regimens and courses of therapy for patients and teaches a knowledge base comprising advisory information useful for the treatment of a patient with different constituents of different therapeutic regimens and generates in the computing device advisory information for one or more therapeutic treatment regimens based on patient information (See page 234, Table 1 and Column 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method and system of *McAndrew et al* and incorporate the teachings of *Pazanni et al* and *Evans et al* for the advantage of providing physicians with a tool to achieve a better level of individual patient health care management with more accuracy and success in the treatment of diseases or medical conditions. *Evans et al* suggests that in order to make optimal decisions about the use of medications in critically ill patients access to a large amount of complex information is required and it is very useful and helpful to utilize computerized decision-support programs to improve the quality of care.

As per claims 2 and 25, *McAndrew* fails to disclose a method or system capable of accepting a user defined therapeutic treatment regimen for a disease or medical condition and generating in a computing device advisory information or the user defined regimen. *Evans et al* teaches that when the physician selects their own treatment plans which is different than the computer recommended treatment, the computer checks the user defined treatment plan and advises the user concerning information for the

Art Unit: 2761

specific therapeutic drugs being proposed by the physician (See Page 234 Col. 1 and 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system and method of *McAndrew et al* and include the user proposed treatment options taught by *Evans et al* for the advantage of allowing the physician to override the recommendations of the system based on the specific knowledge and experience of the physician concerning the patient. *McAndrew et al* provides motivation or allowing physician input on a proposed treatment option and using the computer system for assessing the proposed treatment options and recommending whether or not to accept the proposed treatment option (See Col. 6, lines 39-58). (C2L 35-40, C4L 20-37)

As per claims 3, 26 and 49, *McAndrew et al* fails to disclose entering a non-recommended therapeutic treatment regimen for the disease or medical condition and generating advisory information for the non-recommended therapeutic treatment regimen and including at least one reason for non-recommendation. *Evans et al* teaches that when the physician selects their own treatment plans which is different than the computer recommended treatment, the computer checks the user defined treatment plan and advises the user concerning information for the specific therapeutic drugs being proposed by the physician. *Evans et al* also discloses that the measures of process includes warnings or alerts generated by the computer program alerting the physician to the occurrence of drug allergies, drug overdoses, antibiotic-susceptibility mismatches and the lack of appropriateness of selected drugs (See Page 234 Col. 1 and 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system and method of *McAndrew et al* and include the non-recommended treatment options taught by *Evans et al* for the advantage of allowing the physician to override the recommendations of the system based on the specific knowledge and experience of the physician concerning the patient. *McAndrew et al* provides motivation or allowing physician input on a proposed treatment option and using the computer system for assessing the proposed treatment options and recommending whether or not to accept the proposed treatment option (See Col. 6, lines 39-58).

As per claims 5, 28 and 51, *McAndrew et al* further discloses patient information which includes prior therapeutic treatment regimen information (See Col. 6, lines 52-58).

Art Unit: 2761

As per claim 6, 29 and 69, *McAndrew et al* fails to disclose wherein the listing of available therapeutic treatment regimens for a patient comprises a ranked listing of available therapeutic treatment regimens. *Pazanni et al* discloses a rule-based expert system that recommends drug regimens for treatment of HIV infected patients and teaches a knowledge base comprising a plurality of different therapeutic treatment regimens for a disease or medical condition (See page 359) and generates in the computing device a ranked listing of available therapeutic treatment regimens for the patient (See page 357 Column 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method and system of *McAndrew et al* and incorporate the teachings of *Pazanni et al* for the advantage of providing physicians with information that would allow them to choose a treatment option that will most likely produce the most successful results for a patient.

As per claims 7, 30 and 52, *McAndrew et al* further discloses patient information which includes prior patient information stored in the computing device (See Col. 6, lines 52-58).

As per claim 8, 31 and 53 *McAndrew et al* fails to disclose advisory information including warnings to take the patient off a drug before initiating a corresponding therapeutic treatment regimen and including information clinically useful to implement a corresponding therapeutic treatment regimen. *Evans et al* discloses that when the physician selects their own treatment plans which is different than the computer recommended treatment, the computer checks the proposed treatment plan and advises the user concerning information for the specific therapeutic drugs being proposed by the physician. *Evans et al* also discloses that the measures of process includes warnings or alerts generated by the computer program alerting the physician to the occurrence of drug allergies, drug overdoses, antibiotic-susceptibility mismatches and the lack of appropriateness of selected drugs (See Page 234 Col. 1 and 2). *Evans et al* also discloses providing advisory information useful for the treatment of a patient with different constituents of different therapeutic regimens and generates in the computing device advisory information for one or more therapeutic treatment regimens based on patient information (See page 234, Table 1 and Column 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system and method of *McAndrew et al* and include the warnings or alerts and

Art Unit: 2761

advisory information taught by *Evans et al* for the benefit of providing the physician with information that may be harmful to a particular patient.

As per claim 9, 32 and 54, McAndrew further discloses wherein the computing device comprises a knowledge base comprising patient therapeutic treatment regimen history (See Col. 6, lines 52-58 and Col. 8, lines 38-48).

As per claims 10, 33 and 55, the *McAndrew et al*, fails to disclose wherein the known disease or medical condition is the HIV infection and the use of antiretroviral drugs as a treatment regimen or adversely interacting non-antiretroviral drugs as a treatment regimen. *Pazanni et al* discloses an expert system used in the management of HIV-infected patients and includes the use of antiretroviral drugs and non-antiretroviral drugs in the treatment regimen (See pages 356-358 and Table 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system and method of *McAndrew et al* and include the treatment of a specific disease such as HIV by using multiple drug therapeutic treatment regimens taught by *Pazanni et al*. *McAndrew et al* discloses a system and method for treating any type of medical condition or disease and it would have been obvious to one of ordinary skill in the art that this could include any specific disease or medical condition such as the HIV infection.

As per claims 13, 20, 36, 43, 58 and 65, *McAndrew et al* fails to disclose wherein the known disease or medical condition is one where multiple therapeutic treatment regimens are available to be used singly or in combination in the treatment of the disease or wherein the known disease is the HIV infection. *Pazanni et al* discloses an expert system in the management of HIV infected patients and discloses the treatment of the disease using multiple drug therapeutic treatment regimens (See pages 357-358 and Table 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system and method of *McAndrew et al* and include the treatment of a specific disease such as HIV by using multiple drug therapeutic treatment regimens taught by *Pazanni et al*. *McAndrew et al* discloses a system and method for treating any type of medical condition or disease

Art Unit: 2761

and it would have been obvious to one of ordinary skill in the art that this could include any specific disease or medical condition such as the HIV infection.

As per claims 14-19, 37-42 and 59-64, *McAndrew et al* fails to disclose wherein the known disease or medical condition is cardiovascular disease, pulmonary disease, a neurologic disease, cancer, a urinary tract infection or hepatitis. *Pazanni et al* discloses an expert system in the management of HIV infected patients and discloses the treatment of the disease. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system and method of *McAndrew et al* and include the treatment of a specific disease such as any of the above named diseases since *Pazanni et al* teaches the treatment of at least one specific disease. *McAndrew et al* discloses a system and method for treating any type of medical condition or disease and it would have been obvious to one of ordinary skill in the art that this could include any specific disease or medical condition such as any of the above named diseases.

As per claim 21, 44 and 66, *McAndrew et al* fails to disclose wherein the knowledge base comprises a plurality of different combination therapeutic treatment regimens. *Pazanni et al* discloses a rule-based expert system that recommends drug regimens for treatment of HIV infected patients and teaches a knowledge base comprising a plurality of different combinations of therapeutic treatment regimens for a disease or medical condition (See page 359) and generates in the computing device a ranked listing of available therapeutic treatment regimens for the patient (See page 357 Column 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method and system of *McAndrew et al* and incorporate the teachings of *Pazanni et al* for the advantage of providing physicians with a tool to achieve an improved level of individual patient health care management by offering multiple combinations of drug therapy that will likely achieve the most successful results in the treatment of diseases or medical conditions.

As per claim 22, 45 and 67, *McAndrew et al* fails to disclose wherein drug dosage information is recommended and adjusted if necessary depending upon said patient information. *Evans et al* discloses a computerized program that recommends antiinfective regimens and courses of therapy for patients and

Art Unit: 2761

teaches advisory information useful for the treatment of a patient with a specific disease or medical condition and generates in the computing device advisory information for one or more therapeutic treatment regimens based on patient information including warning and alerts associated with drug doses (See page 234 and Table 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method and system of *McAndrew et al* and incorporate the teachings of *Evans et al* for the advantage of providing physicians with a tool to achieve an improved level of individual patient health care management by providing warnings and alerts concerning drug dosages so that the treatment will achieve the most successful results in the treatment of the disease or medical condition. *Evans et al* suggests that in order to make optimal decisions about the use of medications in critically ill patients access to a large amount of complex information is required and it is very useful and helpful to utilize computerized decision-support programs to improve the quality of care.

As per claims 23, 46 and 68, *McAndrew et al* further discloses accessing via the computing device information for one or more therapeutic treatment regimens including definitions of medical conditions and treatments, detailed articles from medical journals relating to the diagnosis and treatment, policy and clinical guidelines and other relevant information useful in assessing whether a proposed treatment is appropriate for the given diagnosis. It would have been obvious to one of ordinary skill in the art that this documentation could include a drug reference source which is commonly used in the medical field.

As per claim 47, *McAndrew et al* discloses an expert system for providing interactive assistance which is useful in managing the health care of individual patients and teaches a "computer program for guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition and providing patient information to a computing device (See Figure 2, Col. 2, lines 37-41 and Col. 6, lines 29-51) and a knowledge base with a plurality of expert rules for evaluating and selecting a therapeutic treatment regimen for a disease or medical condition" (See Figure 1, Col. 3, lines 6-17 and 49-53, and Col. 7, lines 45-54). *McAndrew et al* also discloses a database of information and synopses which are relevant to the disease or medical condition of the patient (See Col. 6 line 62-Col. 7 line 4 and

Art Unit: 2761

Col. 7, lines 37-44), however, does not explicitly disclose a plurality of different therapeutic treatment regimens for a disease or advisory information useful for the treatment of a patient with different constituents of the different therapeutic treatment regimens. *McAndrew et al* also does not explicitly disclose generating a listing of available therapeutic treatment regimens for the patient. *Pazanni et al* discloses a rule-based expert system that recommends drug regimens for treatment of HIV infected patients and teaches a knowledge base comprising a plurality of different therapeutic treatment regimens for a disease or medical condition (See pages 357 Col. 1 and 359) and generates in the computing device a ranked listing of available therapeutic treatment regimens for the patient (See page 357 Column 1). *Evans et al* discloses a computerized program that recommends antiinfective regimens and courses of therapy for patients and teaches a knowledge base comprising advisory information useful for the treatment of a patient with different constituents of different therapeutic regimens and generates in the computing device advisory information for one or more therapeutic treatment regimens based on patient information (See page 234, Table 1 and Column 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of *McAndrew et al* and incorporate the teachings of *Pazanni et al* and *Evans et al* for the advantage of providing physicians with a tool to achieve a better level of individual patient health care management with more accuracy and success in the treatment of diseases or medical conditions. *Evans et al* suggests that in order to make optimal decisions about the use of medications in critically ill patients access to a large amount of complex information is required and it is very useful and helpful to utilize computerized decision-support programs to improve the quality of care.

As per claim 48, *McAndrew* fails to disclose a computer program capable of accepting a user defined therapeutic treatment regimen for a disease or medical condition and generating in a computing device advisory information or the user defined regimen. *Evans et al* teaches that when the physician selects their own treatment plans which is different than the computer recommended treatment, the computer checks the user defined treatment plan and advises the user concerning information for the specific therapeutic drugs being proposed by the physician (See Page 234 Col. 1 and 2). It would have

Art Unit: 2761

been obvious to one of ordinary skill in the art at the time the invention was made to modify the computer program of *McAndrew et al* and include the user proposed treatment options taught by *Evans et al* for the advantage of allowing the physician to override the recommendations of the system based on the specific knowledge and experience of the physician concerning the patient. *McAndrew et al* provides motivation or allowing physician input on a proposed treatment option and using the computer system for assessing the proposed treatment options and recommending whether or not to accept the proposed treatment option (See Col. 6, lines 39-58).

Allowable Subject Matter

8. Claims 4, 11-12, 27, 34-35, 50 and 56-57 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Also, the 35 U.S.C. 112, second paragraph rejections of claims 4, 27 and 50 detailed above must be overcome.

9. The following is a statement of reasons for the indication of allowable subject matter:

As per claims 4, 27 and 50, the prior art of record taken either individually or in combination fails to teach or suggest wherein patient information includes viral load information, HIV genotype and phenotype information, hemoglobin information, neuropathy information, neutrophil information, pancreatitis, hepatic function, and renal function.

As per claims 11-12, 34-35 and 56-57, the prior art of record taken either individually or in combination fails to teach or suggest wherein the therapeutic treatment regimen the drug terfenadine or the drug cisapride.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Dormond et al discloses an expert system which provides one or more suggested treatments for a patient.

Art Unit: 2761

- Brill et al discloses a system including knowledge bases to determine medications which may be used to relieve symptoms of injuries and illnesses covered by the knowledge base
- Chirico discloses an expert system with a plurality of independent knowledge bases
- Sillen et al discloses a method and system for giving patients individualized, situation dependent medication advice
- Brynjestad discloses a knowledge based expert interactive system for facilitating the diagnosis and treatment of acute and chronic pain

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Hayes whose telephone number is (703)306-5447. The examiner can normally be reached Monday through Friday from 7:30 to 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Voeltz, can be reached on (703) 305-9714.

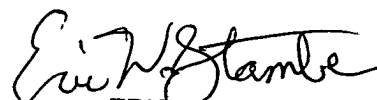
The Fax phone number for the **UNOFFICIAL FAX** for the organization where this application or proceeding is assigned is (703) 305-0040 (for informal or draft communications, please label "PROPOSED" or "DRAFT").

The Fax phone number for the **OFFICIAL FAX** for the organization where this application or proceeding is assigned is (703) 308-9051 or 9052 (for formal communications intended for entry).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3900.

jwh

24 September, 1999


ERIC W. STAMBER
PRIMARY EXAMINER